PT. SINKO PRIMA ALLOY

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User Notice

- Thank you for choosing the company's equipment. In order to ensure safe operation and long-term stability of the instrument performance, it is necessary to fully understand the function,operation and maintenance of the instrument by reading this manual before operating the instrument.
- Particular attention must be paid to the "Warning" and "Caution" in the manual.
- The company is not responsible for any damage or injury caused by improper operation or the user's failure to follow the manufacturer's or its agent's instructions to maintain the instrument.

• Warning!
“Warning” Used to indicate that if ignored, it will cause serious personal injury, death or actual property damage.

• Caution!
"Caution" is used to remind users of installation, operation or maintenanceinformation. This information is very important, but if ignored, it will cause slight personal injury or property damage.

Guarantee

- The company guarantees to users that the warranty period is 12 months from the date of purchase and shipment.
- This guarantee is only applicable to failures that occur when the instrument is operated underthe conditions specified in the manual. Please ensure that the instrument is only used in the scope of use

recommended in the accompanying manual.

- This warranty does not apply to damage to the instrument due to accidents, misuse, abuse, falling, and attempts to modify or change any parts or components of the instrument.
- Damage to the surface of the instrument is not included in the scope of repair or replacement.The cost of supply of training materials, etc. is not included.
- The company is not responsible for damage caused by other instruments or unauthorized connection of other instruments.
- When there is a problem with the company's products during the warranty period, please notify the company, stating the instrument model, serial number, date of purchase and the problem.

Operation Precautions

● Caution!

- Neonatal jaundice treatment instrument (jaundice treatment instrument) can be used incombination with infant incubator.
- Improper use of the jaundice treatment device may cause harm to the patient. The operator of the jaundice treatment device must be specially trained and used under the guidance of qualifiedmedical personnel who are familiar with the commonly known risks and benefits in the use of jaundice lamps.
- It is forbidden to use the jaundice treatment device in the presence of combustion-supporting gas (for example: oxygen, nitric oxide and anesthetic gas).
- The jaundice treatment device cannot be used in a place where a strong electromagnetic field isgenerated, and equipment that is susceptible to

magnetic interference can not be used near the jaundice treatment device.

- Direct sunlight or other radiation sources may affect the patients undergoing treatment. Therefore, the jaundice treatment device cannot be used in places exposed to direct sunlight orother radiation sources.
- It is forbidden to use flammable agents (for example: antiseptics, cleaning agents, etc.) on theequipment.
- In the area irradiated by the light source, it is forbidden to place any medicines and injections.
- The jaundice treatment device cannot use reflective foil. The use of reflective foil will affect the radiation effect of the phototherapy equipment and cause an unexpected rise in body temperature.
- When the jaundice treatment device is used on a baby incubator, it will produce less heat, andunder continuous light irradiation, it will affect the uniform temperature in the incubator, resulting in an unexpected rise in the patient's body temperature. Therefore, the operator needs to regularly measure the patient's body temperature. (It is recommended to be once every hour)
- During use, make sure that the jaundice treatment device is placed firmly. When moving thebaby incubator, the jaundice lamp must be removed
- To ensure the safety and effectiveness of the jaundice treatment device, only the parts providedby our company, such as irradiation light sources, can be used.
- The jaundice meter produces less heat, but under continuous light irradiation, it will still cause an unexpected rise in the patient's body temperature. In addition, when it is used in combination with a warming device, such as an incubator, a warming table, or a heating mattress, it

will affect the temperature uniformity of these warming devices, which may also cause an unexpected rise inthe patient's body temperature. Therefore, the operator needs to regularly measure the patient's body temperature. (The company recommends at least once per hour)

- The service life of the jaundice treatment device is 6 years. The jaundice treatment instrument and its accessories and packaging after the expiration of use will cause damage to the local environment if discarded at will. Therefore, it must be disposed of in accordance with local laws or returned to our company for disposal.
- The purchaser or user of the jaundice treatment device should use the jaundice treatmentdevice in the specified electromagnetic environment, otherwise it may cause the jaundice treatment device to not work normally.
- Portable and mobile radio frequency communication equipment may affect the normal use ofthe jaundice treatment device. Please use the jaundice treatment device in the recommended electromagnetic environment.

• Warning!

Phototeraphy Precautions

- In order to prevent damage to the patient’s retina, the patient must wear an eye mask during thelight period
- During the illumination period, the operator should not look directly at the light source.

Regular Safety Inspection

- Before starting to use, the performance and mechanical integrity of the product should be tested,and at least once every 12 months thereafter, and a record should be made during the test.
- The area between the power plug terminals should be cleaned at least once a year. If dust accumulates between the power plug terminals, it may cause a fire.
- The safety inspection shall be carried out by at least one trained professional and technical personnel with sufficient knowledge and practical experience every year. The test data shall be preserved. If any item of the product is unqualified or not in conformity with the function of the test, it must be repaired.

CONTENTS

1 Symbols and Definitions

1.1 Symbol

	Indicates that "injury or damageto the item may occur" if used incorrectly.		Indicates attention, please consult the random file
	Directly related to user and patient safety		Class II equipment
	Series Number		Manufactuer
	Should not be disposed of with household waste.		A mark indicating reading theproduct manual for this product
	Eye protection must be worn for the patient	 B	B for blue light abbreviation, this is the on and off key of blue light
	Blue light intensity adjustment		Blue light timing adjustment
 W	W for White light this is the onand off key of white light		White light Illumination enhancement
	White light Illuminationreduction	DC	Direct current

AC	Alternating current		Handle with care
	Afraid of rain		Put up
	Stacking layer limit		Do not step on
G.W	Gross weight	DIM	Size

1.2 Definitions

- Infant phototherapy equipment

The main radiation spectrum emitted is in the range of 400 nm to 550 nm, which is used to reducethe concentration of bilirubin in infants.

- Effective light area

The surface used to place the patient in a designated position, and the surface is irradiated by thephototherapy equipment.

Note: "Effective illumination area" is the designated treatment surface illuminated by thephototherapy lamp.

- Total bilirubin irradiance **Ebi** total irradiance for bilirubin **Ebi**

The irradiance is equivalent to the irradiance evaluated in the range of 400 nm to 550 nm,expressed by the following integral:

$$Ebi = \int_{400nm}^{550nm} E\lambda(\lambda)d\lambda$$

Eλ(λ) is the irradiance measured at each wavelength (λ), in W/m2.

- Uniformity of total bilirubin irradiance G2

In the effective light area, the ratio of the lowest total bilirubin irradiance Ebi min and the highest total bilirubin irradiance Ebi max is represented by the following equation

Show: G2=Ebi min/Ebi max

- Light source lifetime: the time after the total bilirubin irradiance Ebi has decayed by 25%

2 Overview

The neonatal jaundice treatment instrument is suitable for light therapy of premature infants and neonatal hyperbilirubinemia. Jaundice is a common phenomenon in the neonatal period. It is observed that more than 90% of newborns can have different degrees of jaundice. It can be a physiological phenomenon in the newborn period (called physiological jaundice). It can also be an important symptom of many diseases in the neonatal period (called pathological jaundice). Because this pathological jaundice can cause bilirubin encephalopathy (kernicterus) and cause brain damage in infants, leading to early death and serious sequelae, it is necessary to make timely and effective treatment of neonatal pathological jaundice.

The effect of light therapy on neonatal hyperbilirubinemia (hyperbilirubinemia) is clinically recognized. The principle is that bilirubin can absorb light to produce photochemical isomerization,so that indirect bilirubin can be oxidized into a water-soluble product under the action of blue light.It is recognized by the medical community that phototherapy is an effective method for the treatment of neonatal pathological jaundice, and it is an indispensable medical device for every medical unit.

The BL-10 series neonatal blue light therapy device adopts 400-475 nm LED light source, which is the latest high-efficiency, energy-saving and long-life product developed by our company. The product complies with GB 9706.1-2007 "Medical Electrical Equipment Part 1: General Requirements for Safety" and the special safety requirements for neonatal blue light therapy devices should comply with YY0669-2008 Medical Electrical Equipment Part 2: Special Requirements for the Safety of Infant Phototherapy Equipment; electromagnetic Compatible with YY 0505-2012.

2.1 Technical Data

Electrical spesification	Power supply	AC 110 ~ 240 V 50/60HZ
	Input power	80 VA
Perfomance specification	Light source	Blue LED/ White LED
	LED lamp lifetime	50000 hours
	LED lamp quantity	48 pcs (24 blue/24 white)
	Count down time range	10-60 mins
	Irradiance control	5 levels
	Radiant wavelength	400 nm - 500 nm
	Peak of wavelenght	452 nm - 455 nm
	Infrared radiation in effective area	≤10 mW/cm^2 (760 nm<λ≤1400 nm)

	Ultraviolet radiation in effective area	≤1.0x10-5 mW/cm^2 (200 nm<λ≤400 nm)				
Irradiance performance (Irridiance distance = 35 cm)	Efective area	300 x 500 mm				
	Uniformity of Ebi	>0.4				
		Level 1	Level 2	Level 3	Level 4	Level 5
	Spectral irradiance intensity (µw/cm^2/nm)	40	51	58	73	83
	Ebi max (maximum total irradiance for bilirubin) (µW/cm^2)	Level 1	Level 2	Level 3	Level 4	Level 5
		2700	3300	3700	4600	5100
Irradiance performance (Irridiance distance = 50 cm)	Efective area	300 x 500 mm				
	Uniformity of Ebi	>0.4				
		Level 1	Level 2	Level 3	Level 4	Level 5
	Spectral irradiance intensity (µw/cm^2/nm)	29	35	38	52	60
	Ebi max (maximum	Level 1	Level 2	Level 3	Level 4	Level 5

	total irradiance for bilirubin) ($\mu W/cm^2$)	1800	2200	2400	3200	3700
Physical specification	Lamphead	540 X 300 X 28 mm				
	Phototeraphy source adjust range	1140 ~ 1690 mm				
	Phototeraphy source rotation angle range	0 ~ 360°				
	Monted type	Mobile (opion: different base, vertical pole), Rail clamp, Table clamp, Wall mounted, Ceiling				
Dimensions		670 x 567 x 1690 mm				
Weight		±8 kg				
Working condition of circumstance	Temperature range	+18℃ ~ +30℃				
	Humidity range	10% ~ 85%				
	Atmosphere pressure	700 hPa ~ 1060 hPa				
Transport and storage condition	Temperature range	-10℃ ~ +55℃				
	Humidity range	≤95%				

	Atmosphere pressure	500 hPa ~ 1060 hPa

2.2 Product Features

a) Classified according to the type of protection against electric shock: Class II;

b) According to the degree of protection against electric shock: the equipment has no applied part;

c) Classification according to the degree of protection against ingress of liquid: ordinary equipment;

d) The equipment cannot be operated under flammable anesthetic gas mixed with air or flammableanesthetic gas mixed with oxygen or nitrous oxide;

e) Classified by operating mode: continuous operation;

f) Rated voltage and frequency: AC 110 ~ 240 V 50/60HZ

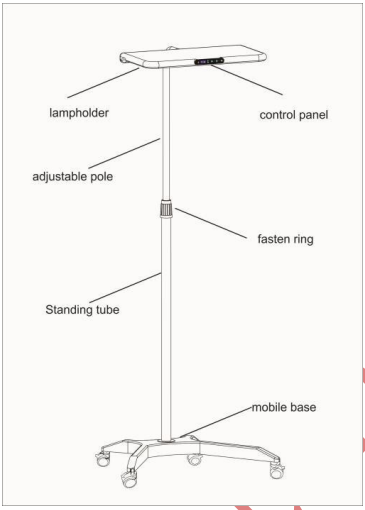
g) Equipment input power: 80 VA;

h) The equipment does not have an applied part to protect against the discharge effect of thedefibrillator;

i) The device does not have a signal output or signal input part

2.3 Main structure

The product is mainly composed of blue light source, control box, supporting part and base.



2.4 Scope of application

It is used for the treatment of jaundice caused by excessively high blood bilirubin concentration in newborns caused by pathological and/or physiological factors.

2.5 Contraindications

Nothing found yet

3 Perfomance Parameters

3.1 Contraindications

a) Ambient temperature: +18 ℃～+30 ℃.

b) Relative humidity: 10%～85% RH.

c) Atmospheric pressure: 700 hPa～1060 hPa.

d) Working power supply conditions: AC 110 ~ 240 V 50/60HZ

e) Input power: 80 VA.

3.2 Basic Parameteres

3.2.1 The outer dimensions of the radiant lamp holder

Lamp head length: 540 mm; width: 300 mm, lamp head swing angle up and down: 320°, horizontalrotation angle left and right: >320°, tolerance: ±5%.

3.2.2 Lighting system

The radiation source of the neonatal blue light therapy instrument consists of 24 blue LED lamp beads and 24 white light LED lamp beads. The blue light is the main illumination light source of thetherapeutic apparatus, and the white light is the auxiliary observation illumination light source.

3.2.3 Wavelength range

The wavelength of the LED light source of the neonatal blue light therapy instrument is in therange of 400 nm～500 nm. The peak wavelength should be 455 nm±5nm

3.2.4 Effective surface

When the blue light is turned on alone, the effective area of the neonatal blue light therapy deviceshould not be less than 24 X 40 cm at a distance of 35 cm from the radiation output surface.

At 50cm away from the radiation output surface, the effective area should not be less than30 X 40 cm.

3.2.5 Maximum total bilirubin irradiance

Maximum total bilirubin irradiance: The output light power of the neonatal blue light therapyinstrument should be adjustable in 5 levels. The maximum total bilirubin irradiance on the effective surface at a distance of 35cm and 50cm from the light source should meet the requirements of Table 1, with errors Not more than ±25%.

3.2.6 Uniformity of total bilirubin irradiance

The uniformity of total bilirubin irradiance on the effective surface G2= Ebi min / Ebi max is greaterthan 0.4.

3.2.7 Auxiliary observation of white light

There are 5 levels of dimming for white light. When the working distance is 35-50 cm, the maximum illumination of white light: >5000 lux, color temperature: 5500-6500K

3.2.8 Noise

Working noise is not more than 60 dB(A).

3.2.9 Timing function

The neonatal blue light therapy instrument is equipped with a timing display of working hours, onegear is 10 minutes, and there are 6 gears in total. The longest timer is 60 minutes.

3.2.10 Height adjustment range

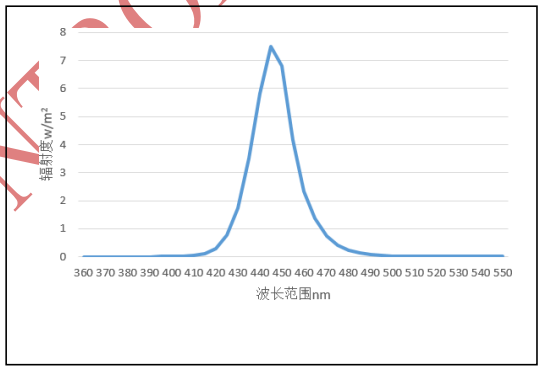
The height of the neonatal blue light therapy instrument can be adjusted, and the height adjustment range is 1140mm (when the telescopic rod is lowered to the lowest) ~ 1690mm (when the telescopicrod is raised to the highest), the allowable error is ±5%.

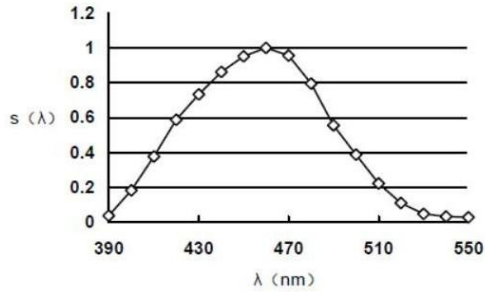
3.2.11 The average value of the wavelength ranges from 380nm to 550nm and the wavelength interval is 5nm.

380	0.00068	470	0.740239
385	0.00347	475	0.404431
390	0.00382	480	0.236291
395	0.00641	485	0.138762
400	0.01514	490	0.076682

405	0.02438	495	0.046303
410	0.05182	500	0.028763
415	0.11892	505	0.022785
420	0.300877	510	0.017053
425	0.760127	515	0.014159
430	1.737953	520	0.011526
435	3.513861	525	0.011909
440	5.824381	530	0.012415
445	7.501207	535	0.012958
450	6.809004	540	0.010775
455	4.167444	545	0.011567
460	2.340476	550	0.010074
465	1.381883		

Unit： W/M^2





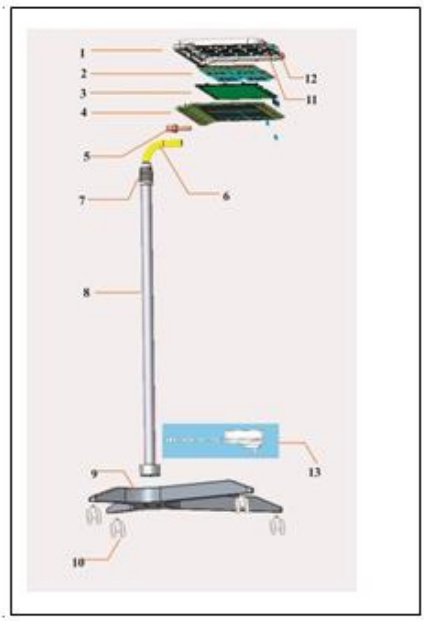
3.2.12 Measurement equipment integration Ebi integration calibration curve

4 Installation and Use

4.1 Product installation diagram

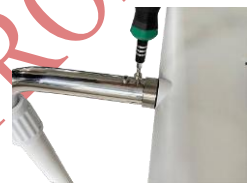
No.	Description of parts	Quantities
1	the upper side of lamp holder	1
2	LED light source panel	4
3	Transparent pmma board	1
4	the down side of lamp holder	1
5	Connector of holder	1
6	Stainless steel rod	1
7	Fasten circle of lifting	1
8	Stand Tube	1
9	Mobile base	1
10	Castors with break	4
11	Digital control PCB	1
12	Control panel	1

13	Electronic Adaptor	1



4.2 Assembly Steps

1. Take out the base and wheels, and install the 4 wheels on the base	2. The wheels are installed	3. Take out the lift riser
		
4. Insert the riser into the fixing	5. Fix the 3 screws at the bottomof the	6. Take out the lamp head and connect

hole of the base, and lock the fixing screws from the bottom of the base.	base, and the installation of the mobile base is completed stand up.	the lamp head wire connector to the lift rod outlet wire connector
		
7. Insert the connection port ofthe square lamp head into the lift rod tube.	8. Align the fixing holes and fixthem with 2 hex screws	9. The lamp head is connected to the mobile base
		
10. The lamp head and lifting pole can be flexibly rotated	11. Take out the adapter, insertthe connector into the wire socket of the outlet of the base pole, and then rotate to fix the	12. After the adapter is installed, you can plug the adapter into the power outlet to power on.

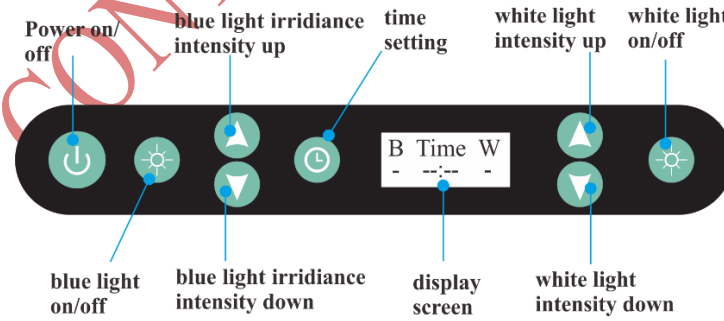
	connection	
		

4.3 Instruction

a. Take out the adapter, insert the connector into the interface on the control box, and rotate the fixing ring to fix it. The adapter plugs into the AC220's power supply.

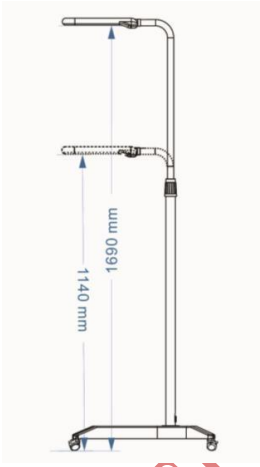
b. Lightly press the blue light switch on the control panel of the lamp head, press the blue light timing setting button, you can see the timing time on the display screen, there are 5 levels in total, each level is 10 minutes, and the longest time is 60 minutes. Follow the instructions below.

c. When you need to observe the baby's jaundice, you can turn off the blue light switch and turn onthe white light switch to adjust the white light to a suitable brightness for observation.



d. The height of the neonatal blue light therapy device is adjustable, Height adjustment range is 1140mm (when the telescopic rod is lowered

to the lowest level) ～1690mm (when the telescopic rod is raised to the highest), the allowable error is ±5%.



e. Swing angle of lamp head up and down: 320º,Horizontal rotation angle left and right: >320º, Tolerance: ±5%.

4.4 Precautions before operation Cau

- Confirm that the jaundice treatment instrument has been cleaned and disinfected in accordancewith Article 5.1 of this manual.

- Confirm that the jaundice treatment device can work normally. The light source can be bright, andthe timer can count normally.
- The jaundice treatment device should be used at an ambient temperature of +18℃~+30℃. It cannot be used in an environment with direct sunlight, strong electromagnetic fields or other radiation sources, otherwise it will affect the patient.
- Nursing staff can adjust the irradiation treatment distance according to clinical needs, but the change of the distance will cause a certain degree of total irradiance on the crib surface. Impact.
- To ensure the safety and effectiveness of phototherapy for patients, the distance between theradiation source of the jaundice lamp and the baby should be kept at 35cm

  Within ~50cm.

- In order to achieve the best light treatment effect, it is necessary to ensure that the center pointof the jaundice lamp radiation light source is in the same position as the center point of the baby's effective surface. A vertical line.
- When used with incubators, baby radiant warmers or heated mattresses, it is recommended to usethe skin control mode. Otherwise, according to body temperature
- As a result, it is necessary to reduce the setting of the air temperature in the incubator or the setting of the heat output of the radiant warmer or the setting of the heat output of the heated mattress.
- Put the naked patient on the effective surface of the crib.

Note: In order to achieve the best phototherapy effect, the patient must be completely within the effective surface. The area size of the effective surface and its.

The distance of the light source affects the average value of the total bilirubin irradiance, the largerthe effective surface is, the smaller the average value, and the longer the distance, the smaller the average value; vice versa on the contrary.

- Use protective devices to prevent patients from leaving the effective surface area, such as the cribbaffle, the front door of the infant incubator, and regularly check the safety functions.
- After the above operations are handled properly, the operator should promptly exit the area wherethe light can be irradiated to avoid long-term exposure to light radiation. If you need to When re-operation of the equipment or patient care/examination is required, the irradiating light source should not be looked directly at.
- Turn on the power supply of the device and turn on the power switch of the device, and the devicewill begin to perform phototherapy on the patient.

  Note: The time of phototherapy should follow the instructions of the attending doctor.
- Warm-up time is 5 hours, debugging time is 0.5 hours

 Warning

- The direct irradiation of the light source of the equipment will cause damage to the eyes of the patients, and the patients near the equipment and the patients during the illumination period mustbe worn Protective

eyewear to prevent patients from developing symptoms such as photo-induced keratitisor retinal heat damage.

- During the light period, diapers or other similar items must be used to cover the patient's genitalsto prevent damage to the patient's genital function.
- During the light period, the water balance in the patient's body may be disrupted, and the nursingstaff should replenish the patient's water in time.
- During light, photoisomers of bilirubin may cause toxic effects. For example, patients mayexperience diarrhea, kernicterus deficiency. With symptoms such as hemolysis and anemia, nursing staff should strengthen monitoring.
- The bilirubin value of the patient should be measured regularly.
- To avoid dizziness, nausea, blurred vision and other discomforts, nursing staff should not stay inthe light-irradiated area for too long

5 Cleaning and Maintenance

5.1 Cleaning

When the equipment is used for the first time, or the equipment has been used continuously forone week, it must be thoroughly cleaned and disinfected.

Before performing the cleaning procedure, the connection between the equipment and the powersupply must be cut off, and the power switch of the equipment must be turned off.

General formula	Maximum concentration
Sodium hypochlorite (bleached)	0.5% aqueous solution

Glutaraldehyde	2%
hydrogen peroxide	6%
Iodine solution	0.27%

Caution

a. If you use cleaning/disinfecting solvents with chemical components not listed in the above table (such as ethanol, acetone, etc.), or the concentration of the chemical components exceeds the valuelisted in the above table, it may damage the equipment.

b. Do not immerse the parts in cleaning solvents. Be sure to wipe off all cleaning solvents on the parts. Following these two recommendations can greatly extend the life of the components.

c. Any parts cleaned with iodine solvent will produce yellow stains.

d. Do not let too much cleaning solvent leak to the position between the plastic parts that is not easy to wipe with a cloth.

e. The translucent board cannot be polished or cleaned with high-alkali detergent, benzene, gasoline, acetone, carbon tetrachloride, butyl cellosolve, only a soft cleaning cloth and neutral soap.

5.2 Maintenance

5.2.1 At least once a year, a trained professional with sufficient knowledge and practical experience shall measure the total bilirubin irradiance of the jaundice treatment device, and perform electrical safety and inspection in accordance with the requirements in YY0669 and GB9706.1 Calibration of irradiance.

5.2.2 The lifetime of the light source is 50000 hours. After the light source has exceeded its life span, in order to ensure the effect of phototherapy, it must be completely replaced even if it still works

normally. This is because: the light irradiation abilityof the light source will gradually decline with the extension of working hours, which will cause the total bilirubin irradiance of the jaundice treatment device to attenuate by about 25%, which will leadto the use of this device for light therapy of patients It may lose the expected effect. The replacementof the light source should be submitted to authorized and qualified maintenance personnel.

5.2.3 Regular and preventive inspections: check every two months to check the fasteners of each connection part of the product to prevent accidents due to their looseness, and check the panel function and power input interface. Before each startup, check the working environment of the blue light and whether the wiring is correct, etc., to ensure safety before the startup.

5.3 Common faults and solutions

5.3.1 When the instrument fails to work normally, do not disassemble or assemble it easily, and contact the customer service department of our company in time to find out the cause of the failure.

5.3.2 Before requesting repair service, please check the instrument according to the table below tosee if you can handle the problem yourself.

Phenomenon	Cause Analysis	Solution
The switch is on, butthe light is off	1. The power is notplugged in	1.Check whether the power supply is normal 2. Check if the power cord is properly

		connected
	2. Power failure	Turn off the power switch and turn it on again after a call
	3. Control circuit failure	Check whether the control panel function is displayed and whether it is normal
The blue light works normally but the child's jaundice subsides and is ignored	1. The cause of the child's own condition	Cooperate with the doctor to treat according to the condition
	2. The surface of thelamp holder is not clean	Wipe the lamp cap immediately

6 Storage and Transportation

6.1 Storage

The instrument should be stored in the original packaging box and placed in a well-ventilated cleanroom. The packaging box should be high. The ambient temperature is -10°C～+55°C, the relative humidity is ≤95%RH, and the atmospheric pressure is 500 hPa~1060 hPa. No harmful gases, flammable, explosive materials and corrosive gases are allowed.

6.2 Transportation

The instrument in the packaging condition is suitable for road, railway, aviation and waterway transportation. During loading and unloading and transportation, it should be protected from severe vibration and shock, and it should not be exposed to moisture, and it should not be mixed or transported with flammable and corrosive substances. The specific requirements shall be as stipulated in the order contract.

7 After Sales Service

7.2.1 After purchasing the instrument, you need to fill in the warranty card and send it to the manufacturer or agent to have the warranty effect; it is a product quality problem of our company from the date of issuing the invoice. The free warranty period of the product is one year. Calculatedon the day the invoice is issued. (Note: Warranty with purchase invoice and warranty card)

7.2.2 The following conditions are not within the scope of the warranty, and paid maintenance is implemented. Failure caused by man-made damage, improper operation or irresistible natural disasters. Failure caused by remodeling, disassembling, and assembling the product by yourself.

7.2.3 After the warranty period expires, please contact the manufacturer directly to provide serviceguarantee.

7.2.4 To repair this machine, you must contact the customer service department of our company, donot repair it without authorization, open the package by yourself, our company does not provide warranty.

INFANT PHOTOTHERAPY UNIT

BL-10

MANUAL BOOK

Elitech® TECHNOVISION